

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
PAUL FENSTER  
FENSTER & COMPANY, INTELLECTUAL PROPERTY  
LTD.  
P.O. BOX 10256  
PETACH TIKVA, 49002  
ISRAEL

# PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 330/04150		Date of mailing (day/month/year) <b>04 DEC 2006</b>
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/IL05/00380	International filing date (day/month/year) 07 April 2005 (07.04.2005)	Priority date (day/month/year) 07 April 2004 (07.04.2004)
International Patent Classification (IPC) or both national classification and IPC IPC: A61B 5/00( 2007.01),5/103( 2007.01),5/117( 2007.01);A61B 10/00( 2007.01) USPC: 600/304,551,588,591		
Applicant BARNEV LTD.		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☒ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion  16 October 2006 (16.10.2006)	Authorized officer Robert L. Nasser <i>J. Roberts</i>  Telephone No. 571-272-3700 <i>for</i>
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Form PCT/ISA/237 (cover sheet) (April 2005)

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

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**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 135-138

because:

☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require an international search (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 135-138 are so unclear that no meaningful opinion could be formed (*specify*):

These claims are not examined because they are omnibus claims and a meaningful opinion cannot be formed.

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☐ no international search report has been established for said claims Nos. \_\_\_\_\_

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims <u>1-113,116-119,122-134 and 139-141</u>	YES
	Claims <u>114,115,120 and 121</u>	NO
Inventive step (IS)	Claims <u>1-113,116-119,122-134 and 139-141</u>	YES
	Claims <u>114,115,120 and 121</u>	NO
Industrial applicability (IA)	Claims <u>1-34 and 139-141</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Please See Continuation Sheet

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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

**V. 2. Citations and Explanations:**

Claims 1-39 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest determining the specification discrete labor state from a plurality of position signals over a plurality of contractions, as claimed.

Claims 40-55 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest modifying a labor treatment based on a parameter of a representation of labor progression.

Claims 56-75 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest determining the change in magnitude of the position signal with a contraction.

Claims 76-82 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest modifying the dilation measurement, as claimed.

Claims 83-87 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest determining full dilation when the cervix moves with a predetermined motion.

Claims 88-91 the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest determining the relative position of the fetal head, as claimed.

Claims 92-103 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest determining labor progress from geometric and non-geometric data.

Claims 104-107 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the method for determining fetal head deformation.

Claims 114, 115, 120, and 121 lack novelty under PCT Article 33(2) as being anticipated by Paltieli. Paltieli teaches a method of

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**Supplemental Box**

**In case the space in any of the preceding boxes is not sufficient.**

determining the degree of effacement of the cervix from positional information, which is measured manually during an intervention.

Claims 108-113 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the device for detecting the second stage of labor.

Claims 116-119 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest determining the particular parameters from positional information, as claimed.

Claims 122-125 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the filtering method recited.

Claims 126-134 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the pharmaceutical control method.

Claims 139-141 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the data presentation method claimed.

Claims 1-134 and 139-141 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.